K091404

510(k) Summary

APR 22 2010

Optovue, Incorporated
iVue

This 510(k) summary for the iVue is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

General Information

Manufacturer:

Optovue, Inc.
45531 Northport Loop West,
Fremont, CA 94538
Phone: (510) 623-8868
Fax: (510) 623-8668
Registration No.: 3005950902

Contact Person:

Azimun Jamal
Regulatory Manager
Optovue, Inc.
Phone: (510)623-8868 x188
e-mail: azimun_jamal@optovue.com

Device Information

Classification: Class II

Trade Name: iVue

Common Name: Optical Coherence Tomography (OCT)

Classification Name: Ophthalmoscope, a-c powered (21 CFR§ 886.1570)

Predicate Devices

(1) RTVue (K062552)
(2) CA (K071250)

Intended Use

The iVue is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, optic disc, cornea, and anterior chamber of the eye as an aid in the diagnosis and management of ocular diseases.

Device Description

iVue is a modification of its predicate device RTVue (K062552). The intent of use, system performance, majority sub-assemblies, and key components of the iVue are all the same as RTVue. The intention of this redesign is to make the size of the iVue more compact and more affordable.

iVue also has a cornea lens adapter, like the predicate device CA (K071250), which can be attached to the front of the instrument to enable the iVue to image the cornea and anterior chamber of the eye.

iVue, based on the same Optical Coherence Tomography (OCT) technology that is using in the predicate device RTVue (K062552) and CA (K071250), is a non-invasive diagnostic device for viewing the ocular tissue structure with micrometer range resolution. Both iVue and RTVue are designed and manufactured by Optovue Inc. A brochure of the RTVue and CA system is in appendices [1].

Like RTVue, iVue is a computer controlled ophthalmic imaging system. RTVue uses a desktop computer while iVue uses a laptop computer. The device scans a patient's eye and uses a low coherence interferometer to measure the reflectivity of the retinal tissue. The cross sectional retinal tissue structure is composed of sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices. The patient will rest their head on the forehead and chin rest while the operator uses joystick to align the device to patient's eye. The computer has a graphic user interface for acquiring and analyzing the image.

iVue also has similar scan patterns and analysis functions as used in RTVue.

Safety

The power of the scanning beam entering into patient's pupil is at same level as predicate devices. There is no change in the safety from previously submitted devices, the RTVue (K062552) and CA (K071250). A copy of the previous safety analysis for RTVue is attached in the Appendix [2]. The analysis was completed by an international recognized expert in the field of optical radiation hazards and safety, Dr. Dave Sliney.

Effectiveness

The predicate device has been routinely used in clinic. Numerous clinical papers and data have been published over last 2 years. Since there is no performance change, the effectiveness in clinical use is the same as predicate devices. A clinical comparison report and the IRB approved test protocol are attached in the premarket notification.

Substantial Equivalence

The iVue is substantially equivalent to the predicate devices identified previously. The iVue is substantially equivalent to the predicate devices with regard to intended use, operating principle, function, material, and energy source. The only difference from the predicate device is that the iVue is more compact in size.

Performance Data

(a) Non-clinic tests:

The iVue has had accuracy tests, optical emission safety analysis, electrical safety, electromagnetic compatibility test, and software validation tests.

(b) Clinical tests:

Description of Precision Study, Subject Selection Criteria and Pathologies

Instruments:
Two types of Fourier Domain OCT devices were used in the study. The iVue device is a new OCT device and is compared to the predicate device, the RTVue. For the study, three iVues were paired with three RTVues with three different operators and results were compared in normal eyes, and eyes with retina pathology, cornea pathology, and glaucoma.

Scans:
The iVue device has three scan patterns optimized to evaluate three ocular pathologies, namely, i) Cornea scan, ii) Retina scan, and iii) Glaucoma scan. These scan patterns were compared to three equivalent RTVue scans, i) Pachymetry scan, ii) EMM5 scan, and iii) ONH scan, respectively. The measurements and parameters calculated from these respective scans were the same. Both eyes were scanned in each subject.

Subjects:
Four types of subjects were enrolled in the study at two clinical sites, namely 1) normal healthy eyes with no ocular pathology, 2) glaucoma patients, 3) retina patients, and 4) cornea patients. Normal subjects were free from ocular pathology as determined by the Principal Investigator (PI) at each clinical site. Glaucoma patients were diagnosed as having glaucoma by the PI at each site. Retina patients included subjects with any type of retina pathology diagnosed by the PI. Retina pathologies included but were not limited to, AMD, DME, and ERM. Cornea patients included subjects with any type of cornea pathology as diagnosed by the PI, or cornea alteration including LASIK. There were 4 normal subjects, 4 cornea patients, 4 retina patients, and 4 glaucoma patients enrolled for each pair of iVue and RTVue devices. There were 3 pairs of iVue and RTVue devices at 2 clinical sites. At one site, there were 2 iVues systems, 2 RTVues systems and 2 operators at different times. In total, there were 16 subjects enrolled for each of the 3 pairs of iVue and RTVue devices; a total of 48 subjects were included in the study.

Selection Criteria:
All data was carefully reviewed for completeness and quality in two levels, namely, the subject level and the individual scan level. At the subject level, the CRF was carefully reviewed to qualify each subject against all inclusion and exclusion criteria by comparing the study protocol with the CRF. At the individual scan level, the data was reviewed for quality to ensure data meeting inclusion criteria was accepted.

In a clinical environment, only scans with acceptable quality should be used. In order to match our analysis with acceptable clinical results, we reviewed and excluded all scans in the study with poor image quality. Image quality is based on a number of factors, including overall signal strength, localized weak signals, eye blink, data out of boundary, and data off-center. Due to the selection criteria, the sample size for each scan type varies.

Precision Results

The following tables provide the precision results for the iVue scans. The data in the table includes the number of scans per subject group, the overall mean, the standard deviation, the repeatability standard deviation (Median value of subfields with the minimum subfield value and the maximum subfield value), and reproducibility standard deviation (Median value of subfields with the minimum subfield value and the maximum subfield value).

i) Glaucoma Scan Results (Normals and Glaucoma Patients)

The following table shows the overall precision results with the Glaucoma scan for average RNFL thickness for normals and glaucoma patients.

Avg RNFL	Normal Patients	Glaucoma Patients
# of Scans	72	65
Overall Mean (Overall SD)	100.26 (8.32)	85.94 (14.40)
Repeatability SD* (Min, Max)	1.30 (1.30, 1.30)	1.09 (1.09, 1.09)
Reproducibility SD** (Min, Max)	1.30 (1.30, 1.30)	7.03 (7.03, 7.03)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning.
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the maximum reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

The following table shows the overall precision results with the Glaucoma scan for the average of 16 sectors for normals and glaucoma patients.

16 RNFL Sectors	Normal Patients	Glaucoma Patients
# of Scans	72	65
Overall Mean (Overall SD)	100.26 (16.33)	85.94 (18.68)
Repeatability SD* (Min, Max)	3.74 (3.74, 5.82)	3.58 (3.58, 6.13)
Reproducibility SD** (Min, Max)	5.29 (4.27, 14.04)	7.56 (3.58, 17.32)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the maximum reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

ii) Retina Scan Results (Normals, Retina Patients and Glaucoma Patients)

The following table shows the overall precision results with the Retina scan for full retinal thickness in the fovea for normals, retina patients, and glaucoma patients (since inner retinal layer is affected by the disease of glaucoma, the precision results of retina scan on glaucoma patients are produced below).

Full Retina Fovea	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	72	71	67
Overall Mean (Overall SD)	247.00 (26.03)	269.28 (70.95)	247.93 (21.20)
Repeatability SD* (Min, Max)	2.54 (2.54, 2.54)	4.41 (4.41, 4.41)	3.33 (3.33, 3.33)
Reproducibility SD** (Min, Max)	17.41 (17.41, 17.41)	13.73 (13.73, 13.73)	3.33 (3.33, 3.33)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

The following table shows the overall precision results with the Retina scan for full retinal thickness in the periphery (average over 8 sectors outside the fovea) for normals, retina patients, and glaucoma patients.

Full Retina Peripheral	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	72	71	67
Overall Mean (Overall SD)	295.03 (16.95)	298.35 (30.99)	281.55 (24.90)
Repeatability SD* (Min, Max)	1.89 (1.89, 3.04)	2.60 (2.60, 4.11)	2.24 (2.24, 3.33)
Reproducibility SD** (Min, Max)	2.65 (1.89, 10.10)	3.18 (2.60, 4.11)	2.99 (2.24, 8.95)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the maximum reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

The following table shows the overall precision results with the Retina scan for inner retinal thickness in the fovea for normals, retina patients, and glaucoma patients.

Inner Retina Fovea	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	72	71	67
Overall Mean (Overall SD)	72.91 (14.36)	77.88 (20.64)	72.35 (10.28)
Repeatability SD* (Min, Max)	2.94 (2.94, 2.94)	3.14 (3.14, 3.14)	1.99 (1.99, 1.99)
Reproducibility SD** (Min, Max)	8.96 (8.96, 8.96)	3.14 (3.14, 3.14)	1.99 (1.99, 1.99)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

The following table shows the overall precision results with the Retina scan for inner retinal thickness in the periphery (average over 8 sectors outside the fovea) for normals, retina patients, and glaucoma patients.

Inner Retina Peripheral	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	72	71	67
Overall Mean (Overall SD)	118.01 (9.37)	117.37 (13.83)	106.73 (12.05)
Repeatability SD* (Min, Max)	1.45 (1.45, 2.82)	1.91 (1.91, 3.41)	1.88 (1.88, 2.83)
Reproducibility SD** (Min, Max)	3.19 (2.22, 5.32)	3.26 (1.91, 5.20)	2.37 (1.88, 2.83)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the maximum reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

iii) Cornea Scan Results (Normals and Cornea Patients)

The following table shows the overall precision results with the Cornea scan for central 0-2 mm cornea thickness for normals and cornea patients.

Central Cornea 0-2 mm	Normal Patients	Cornea Patients
# of Scans	70	72
Overall Mean (Overall SD)	549.83 (20.85)	531.80 (48.20)
Repeatability SD* (Min, Max)	1.71 (1.71, 1.71)	3.58 (3.58, 3.58)
Reproducibility SD** (Min, Max)	1.71 (1.71, 1.71)	14.52 (14.52, 14.52)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning

**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the maximum reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

The following table shows the overall precision results with the Cornea scan for 2-5 mm cornea thickness measurements for normals and cornea patients.

Cornea 2-5 mm	Normal Patients	Cornea Patients
# of Scans	70	72
Overall Mean (Overall SD)	569.23 (22.10)	559.10 (49.50)
Repeatability SD* (Min, Max)	2.42 (2.42, 5.44)	5.27 (5.27, 7.79)
Reproducibility SD** (Min, Max)	4.04 (2.42, 5.44)	21.38 (14.29, 29.19)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning

**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the maximum reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

The following table shows the overall precision results with the Cornea scan for 5-6 mm cornea thickness measurements for normals and cornea patients.

Cornea 5-6 mm	Normal Patients	Cornea Patients
# of Scans	70	72
Overall Mean (Overall SD)	590.93 (24.55)	589.81 (49.69)
Repeatability SD* (Min, Max)	3.63 (3.63, 7.55)	6.50 (6.50, 11.72)
Reproducibility SD** (Min, Max)	5.77 (3.63, 7.55)	24.31 (13.97, 38.47)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning

**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the maximum reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

Agreement Results

The following tables provide the overall agreement results for the iVue scans compared to the RTVue scans. The data in the table includes the overall mean differences averaged across all measurements for that scan pattern (with the minimum and maximum differences provided in parentheses) and the

standard deviation of the differences (with the minimum and maximum standard deviations provided in parentheses).

i) Glaucoma LOA Results

The following table shows the overall agreement results for average RNFL thickness measurement in the iVue Glaucoma scan and the RTVue ONH scan for normals and glaucoma patients.

Avg RNFL	Normal Patients	Glaucoma Patients
Mean Differences (Min, Max)	-0.55 (-0.61, -0.49)	-0.52 (-0.87, -0.18)
Estimated STDEV (Min, Max)	2.25 (2.12, 2.38)	1.74 (1.71, 1.76)

The following table shows the overall agreement results for the 16 sector RNFL thickness measurement in the iVue Glaucoma scan and the RTVue ONH scan for normals and glaucoma patients.

16 RNFL Sector Averages	Normal Patients	Glaucoma Patients
Mean Differences (Min, Max)	-0.55 (-8.00, 4.49)	-0.53 (-7.19, 4.25)
Estimated STDEV (Min, Max)	8.16 (6.26, 11.01)	7.61 (5.01, 10.39)

ii) Retina LOA Results

The following table shows the overall agreement results for full retina fovea thickness measurement in the iVue Retina scan and the RTVue EMM5 scan for normals, glaucoma patients, and retina patients

Full Retina Fovea	Normal Patients	Glaucoma Patients	Retina Patients
Mean Differences (Min, Max)	2.64 (1.91, 3.37)	1.99 (1.64, 2.35)	2.14 (1.13, 3.14)
Estimated STDEV (Min, Max)	3.79 (3.39, 4.20)	4.88 (4.60, 5.16)	6.00 (5.36, 6.64)

The following table shows the overall agreement results for full retina peripheral thickness measurements in the iVue Retina scan and the RTVue EMM5 scan for normals, glaucoma patients, and retina patients.

Full Retina Periphery	Normal Patients	Glaucoma Patients	Retina Patients
Mean Differences (Min, Max)	-0.27 (-3.48, 3.21)	-1.00 (-4.18, 2.40)	-0.41 (-2.83, 2.30)
Estimated STDEV (Min, Max)	3.48 (2.28, 4.92)	4.56 (3.66, 5.34)	4.54 (3.70, 5.51)

The following table shows the overall agreement results for inner retina fovea thickness measurement in the iVue Retina scan and the RTVue EMM5 scan for normals, glaucoma patients, and retina patients.

Inner Retina Fovea	Normal Patients	Glaucoma Patients	Retina Patients
Mean Differences (Min, Max)	2.64 (1.91, 3.37)	1.70 (1.58, 1.82)	2.39 (1.92, 2.86)
Estimated STDEV (Min, Max)	3.79 (3.39, 4.20)	4.15 (3.51, 4.79)	4.73 (4.61, 4.86)

The following table shows the overall agreement results for inner retina peripheral thickness measurements in the iVue Retina scan and the RTVue EMM5 scan for normals, glaucoma patients, and retina patients.

Inner Retina Periphery	Normal Patients	Glaucoma Patients	Retina Patients
Mean Differences (Min, Max)	-0.27 (-3.48, 3.21)	-0.50 (-3.22, 2.17)	-0.26 (-2.10, 2.18)
Estimated STDEV (Min, Max)	3.48 (2.28, 4.92)	4.05 (2.70, 5.94)	4.28 (2.93, 5.91)

iii) Cornea LOA Results

The following table shows the overall agreement results for the central 0-2mm cornea thickness measurement in the iVue Cornea scan and the RTVue Pachymetry scan for normals and cornea patients.

0-2 mm Central Cornea	Normal Patients	Cornea Patients
Mean Differences (Min, Max)	-0.44 (-0.64, -0.23)	-1.04 (-1.41, -0.67)
Estimated STDEV (Min, Max)	5.25 (4.86, 5.63)	5.70 (5.63, 5.78)

The following table shows the overall agreement results for the central 2-5 mm cornea thickness measurement in the iVue Cornea scan and the RTVue Pachymetry scan for normals and cornea patients.

2-5 mm Cornea	Normal Patients	Cornea Patients
Mean Differences (Min, Max)	1.27 (-0.74, 2.85)	0.07 (-4.01, 3.72)
Estimated STDEV (Min, Max)	7.93 (4.14, 11.71)	12.35 (7.81, 16.64)

The following table shows the overall agreement results for the central 5-6 mm cornea thickness measurement in the iVue Cornea scan and the RTVue Pachymetry scan for normals and cornea patients.

5-6mm Cornea	Normal Patients	Cornea Patients
Mean Differences (Min, Max)	2.71 (-1.14, 5.05)	1.79 (-3.15, 8.29)
Estimated STDEV (Min, Max)	10.27 (5.39, 13.32)	15.28 (8.99, 21.84)

The evidence from the clinical performance data study demonstrates that the iVue is substantially equivalent to the predicate device, the RTVue.

Conclusion

As described in this 510(k) Summary, comprehensive testing and analysis was conducted on the iVue to ensure that the device is safe and effective for its intended use when used in accordance with its instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Optovue, Inc
c/o Ms. Azimun Jamal
Manager of Quality/Regulatory
45531 Northport Loop W.
Fremont, CA. 94538

APR 22 2010

Re: K091404
Trade/Device Name: iVue Model iVue100
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: April 19, 2010
Received: April 20, 2010

Dear Ms. Jamal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K091404

Device Name: iVue

Indications for Use:

The iVue is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, optic disk, cornea, and anterior chamber of the eye as an aid in the diagnosis and management of ocular diseases.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Neurological and Ear, Nose and Throat Devices

510(k) Number K091404